

Customer No. 28880

Confirmation No.

PTO/SB/21 (03-03)

Approved for use through 04/30/2003. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/731,225
Filing Date	December 9, 2003
First Named Inventor	Charles Price Taylor, Jr., et al.
Art Unit	1614
Examiner Name	Not Yet Known
Attorney Docket Number	PC 25677A

**ENCLOSURES (Check all that apply)**

- |   |  |   |
|---|--|---|
| <input type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input type="checkbox"/> Amendment/Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input type="checkbox"/> Information Disclosure Statement<br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Response to Missing Parts/Incomplete Application<br><input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation<br><input type="checkbox"/> Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) _____ | <input type="checkbox"/> After Allowance Communication to a Technology Center (TC)<br><input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input type="checkbox"/> Other Enclosure(s) (please identify below):<br>Supplemental Information Disclosure Statement PTO/SB/08A (1pg). Statement as provided by 37 CFR 1.97(b) (1pg).<br>Return Postcard |
|---|--|---|

**Remarks**

AUTHORIZATION TO CHARGE THE FEE AND ANY ADDITIONAL FEES AS NECESSARY OR CREDIT ANY OVERPAYMENT TO DEPOSIT ACCOUNT 23-0455 IS HEREBY GIVEN.

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual: Karen DeBenedictis

Signature: *Karen DeBenedictis*

Date: 6/10/04

**CERTIFICATE OF TRANSMISSION/MAILING**

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date: 6/10/04

Typed or printed: Cynthia D. Bernges

Signature: *Cynthia D. Bernges*

Date: 6/10/04

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PC 25677A

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

APPLICANT : Charles Price Taylor, Jr., et al. EXAMINER :  
SERIAL NO. : 10/731,225 ART UNIT : 1614  
FILED : December 9, 2003 PAPER NO. :  
FOR : Alpha2delta ligands for the treatment of fibromyalgia and other disorders

**Statement as Provided by 37 CFR 1.97(b)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

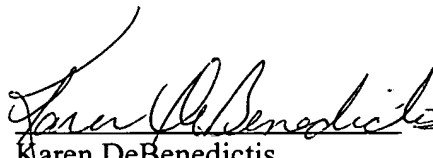
The Applicants submit that a Supplemental Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of the first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

As such, the Applicants respectfully requests consideration of the enclosed Supplemental Information Disclosure Statement and request that all references cited herein be printed on the face of the patent upon grant of the Application.

It is understood by the Applicants that this paper requires no fee; however, authorization is given to charge any necessary filing fees and any additional fees or credit any overpayment to Deposit Account 23-0455.

Respectfully submitted,

Dated: 6/10/04

  
Karen DeBenedictis  
Registration No. 32,977  
Warner-Lambert Company  
2800 Plymouth Road  
Ann Arbor, MI 48105  
Telephone: (734) 622-3374  
Facsimile: (734) 622-1553

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it contains a valid OMB control number.

**Complete if Known**

Application Number	10/731,225
Filing Date	December 9, 2003
First Named Inventor	Charles Price Taylor, Jr., et al.
Art Unit	1614
Examiner Name	Not Yet Known
Attorney Docket Number	PC 25677A

Sheet	1	of	4
-------	---	----	---

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	MM-DD-YYYY			
		EP 0 974 351 A2/A3	01/26/2000	Guglietta, et al		
		WO 00/02546 A2/A3	01/20/2000	Magnus-Miller, et al		
		WO 00/31020	06/02/2000	Belliotti, et al		
		WO 00/67742 A1	11/16/2000	Magistro		
		WO 00/76958 A2/A3	12/21/2000	Belliotti, et al		
		WO 02/100347 A2/A3	12/19/2002	Gallop, et al		

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to office. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO <b>SUPPLEMENTAL</b> <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>		<b>Complete if Known</b>	
Application Number		10/731,225	
Filing Date		December 9, 2003	
First Named Inventor		Charles Price Taylor, Jr., et al.	
Art Unit		1614	
Examiner Name		Not Yet Known	
Attorney Docket Number		PC 25677A	

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
		WO 03/061656 A1	07/31/2003	Galer, et al		
		WO 98/03167 A1	01/29/1998	Singh		
		WO 98/17627 A2/A3	04/30/1998	Bryans, et al		
		WO 99/08670 A1	02/25/1999	Guglietta, et al		

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

**If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO <b>SUPPLEMENTAL</b> <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>		<b>Complete if Known</b>			
		Application Number	10/731,225		
		Filing Date	December 9, 2003		
		First Named Inventor	Charles Price Taylor, Jr., et al.		
		Art Unit	1614		
		Examiner Name	Not Yet Known		
Sheet	3	of	4	Attorney Docket Number	PC 25677A

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		AMERINGEN VAN M., et al., "Drugs in Development for Social Anxiety Disorder More to Social Anxiety Than Meets the SSRI", Expert Opinion on Investigational Drugs, (2000), pp. 2215-2231, Vol. 9(10)	
		BELOZERTSEVA I V, et al., "A Pharmacological study of the GABA-ergic mechanisms regulation the depression-like behavior of mice", US National Library of Medicine, (1997) , pp 1024-1031, Vol. 47	
		BRILEY, et al., "Fibromyalgia Syndrome", Overview of Potential Drug Targets, (2003), pp 668-673, Vol. 6	
		DANILIN V P, et al., "Effect of Fenibut on the nocturnal sleep of patients with the alcoholic abstinence syndrome", US National Library of Medicine, (1986), pp 251-254, Vol. 86( 2)	
		DAVIDSON J.R.T., "Advances and Emerging Treatments in social Phobia", Journal of clinical Psychiatry, (2001), pp. 4, Vol 62(1)	
		FELTNER, et al., "A Placebo-Controlled Double-Blind Study of Pregabalin Treatment of social Phobia", European Neuropsychopharmacology, (2000), pp. S345, Vol. 10(3)	
		GUYMER E K, et al., "An Approach to Managing Fibromyalgia", Medicine Today, (2002), pp. 58-59, Vol. 3(12)	
		HIDALGO, et al., "Social Anxiety Disorder in Review", International Journal of Neuropsychopharmacology, (2001), pp 279-289, Vol. 4(3)	
		KUBOTA, et al, "Pregabalin Enhances Nonrapid Eye Movement Sleep", The Journal of Pharmacology and Experimental Therapeutics, (2001), pp 1095-1105, Vol. 299	
		MARSHALL, et al., "Changes in immune cell counts and interleukin (IL) -1 'beta' production in humans after a somnogenically active growth hormone-releasing hormone(GHRH) administration", Elsevier Science Publishers, (2001), pp 227-234, Vol. 15(3)	

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO <b>SUPPLEMENTAL</b> <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>		<b>Complete if Known</b>			
		Application Number	10/731,225		
		Filing Date	December 9, 2003		
		First Named Inventor	Charles Price Taylor, Jr., et al.		
		Art Unit	1614		
		Examiner Name	Not Yet Known		
Sheet	4	of	4	Attorney Docket Number	PC 25677A

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		MELTZER, et al., "Pregabalin Enhances Non-Rapid Eye Movement Sleep AND EEG Slow-Wave Activity in Rats", Society for Neuroscience Abstracts, (2001), pp 2245, Vol. 27(2)	
		SELAKE I., Pregabalin, Current Opinion in Investigational Drugs, (2001), pp 828-834, Vol. 2(6)	
		VLASOV N. A., "Effects of Derivatives of GABA on Sleep Disturbances in Neurosi", Bulletin of Experimental biology and Medicine, (1978), pp. 169-171, Vol. 85(2)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.